

REMARKS

In the restriction requirement dated November 15, 2006, the Examiner requested restriction under 35 U.S.C. § 121 and 372 to one of the following Groups:

- Group I.** Claims 1-33, drawn to method for modulating androgen receptor comprising administering a therapeutically effective amount of a compound of structural formula I (claim 1) and a bone-strengthening agent;
- Group II.** Claims 14-15, drawn to a compound of structural formula I; and
- Group III.** Claims 16-18, drawn to a composition comprising a compound of structural formula I and a pharmaceutically acceptable carrier and a bone-strengthening agent.

Applicants respectfully traverse the restriction requirement. However, to be fully responsive to the restriction requirement, Applicants elect, with traverse, the subject matter of Group II, claims 14 and 15, drawn to compounds and compositions of formula I. As Group II has been elected, the Examiner further requires an election of a single species from Claims 14 and 15. To be fully compliant with the Examiner's request, Applicants elect, with traverse, 4-methyl-17 $\beta$ -[(4-trifluoromethylphenyl)acetamido]-4-aza-5 $\alpha$ -androst-1-ene-3-one, where: R<sup>1</sup> is methyl, R<sup>2</sup> is trifluoromethylphenyl, R<sup>3</sup> is methyl, R<sup>4</sup> is hydrogen, R<sup>5</sup> is hydrogen, X is -C(O)-, a is a double bond, and b is a single bond. Claim 19 is the general claim.

Criteria for Restriction between Patentably Distinct Inventions

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent (see MPEP §§ 802.01, 808.1) or distinct as claimed (see MPEP §§ 806.05-806.05(i)); and
- (2) There must be a serious burden on the Examiner if restriction is not required (see MPEP §§ 803.02, 806.04 (a) – (j)), 808.01(a) and 808.02).

The Examiner has not shown that there would be a serious burden to examine Groups I, II, and III together. The claims of Groups I-III are directed to a compound of Claim 1. Applicants respectfully submit that a search of the subject matters of Groups I

and III, in addition to the subject matter of Group II, would not be burdensome because a proper search of the subject matter of Groups I and III would necessarily encompass the search of the subject matter of Group II since all claims include a 4-azasteroid compound of Claim 14. Accordingly, Applicants respectfully request that all the claimed species of the 4-azasteroid of Claim 14 continue to be examined in this application.

Should the Office choose to maintain the restriction requirement, Applicants expect the Office, if the elected species is found allowable, to continue to examine the full scope of the elected subject matter to the extent necessary to determine the patentability thereof, i.e., extending the search to a reasonable number of non-elected species in the Markush group, as is the duty according to M.P.E.P. §803.02 and 35 U.S.C. §121.

Applicants respectfully request that the restriction requirement be reconsidered and withdrawn or modified in view of the foregoing comments.

If a telephonic communication with the Applicants' representative will advance the prosecution of the instant application, please telephone the representative indicated below. Applicants believe no additional fees are due but the Commissioner is authorized to charge any fees required in connection with this response to Merck Deposit Account No. 13-2755.

Respectfully submitted,

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